

From: Susan Makris
To: David Bussard
Cc: Vincent Cogliano; Paul White; Bob Sonawane; Jeff Frithsen; Gina Perovich; Charles Ris
Subject: Re: IRIS email re Formaldehyde, and revisions to our assessments
Date: 04/13/2011 10:03 AM

David, Thanks for forwarding this message. The NCEA IRIS e-mail group does not include CMs or team members from NCEA-W, so we would have never seen this message if it had not been forwarded. Additionally, when "all hands" meetings are held in IRIS, NCEA-W staff members aren't invited to participate and the information from those meetings does not get passed along to NCEA-W staff in any formal way. This is a communication gap that really needs to be addressed if we are to build consistency up front in IRIS documents. Sue

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▼ David Bussard---04/13/2011 06:10:02 AM---I can't tell if Cogliano's "NCEA IRIS" group includes all working on IRIS assessments, or just those

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Date: 04/13/2011 06:10 AM
Subject: IRIS email re Formaldehyde, and revisions to our assessments

I can't tell if Cogliano's "NCEA IRIS" group includes all working on IRIS assessments, or just those reporting through the NCEA IO.

So, my apologies if you have already received the below email.

I thought all might be interested to see Vince's message and if any don't have a copy of the recent NRC report, one is attached.

David

----- Forwarded by David Bussard/DC/USEPA/US on 04/13/2011 06:01 AM -----

From: Vincent Cogliano/DC/USEPA/US
To: (b) (6)
Cc: Becki Clark/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, (b) (6) Martin Gehlhaus/DC/USEPA/US@EPA
Subject: Formaldehyde, and revisions to our assessments

Hello everyone -- You've probably heard about the review of our formaldehyde assessment released last Thursday by the National Academy of Sciences. I would like everyone to read the NAS report, attached here.



Formaldehyde Prepub.pdf

Many of the NAS's comments on formaldehyde apply equally to our other assessments. Their report includes a section, "Future assessments and the IRIS process" (pp 113-123), which offers suggestions for how we complete draft IRIS assessments.

This week's all-hands meeting will discuss the proposed IRIS reorganization with union officials invited. At the next all-hands meeting I would like to begin our discussion of the NAS's general recommendations for IRIS. We have discussed some of these themes before, particularly streamlining our assessment documents, and there are other specific recommendations. Although it is painful to read the NAS's criticisms, I am appreciative -- even excited -- about their general recommendations and am confident that we can use them to improve our process and our assessments.

I remain a pragmatist and do not wish to restructure documents already drafted. That said, all chemical managers should give immediate attention to two recommendations: for strengthened discussions of weight of evidence and for expanded rationales for study selection in calculating toxicity values. To illustrate the urgency, appended to this message is the NAS press release, and I will forward the stories that ran in Greenwire and in InsideEPA. We cannot leave ourselves open to further criticism on these points.

Thank you all for your dedication to IRIS. See you soon,
Vincent

Date: April 8, 2011

EMBARGOED: NOT FOR PUBLIC RELEASE BEFORE 11 A.M. EDT FRIDAY, APRIL 8

EPA's Draft Health Assessment for Formaldehyde Needs Improvement

WASHINGTON — A U.S. Environmental Protection Agency draft assessment of the potential health effects associated with formaldehyde exposure needs substantial revision, says a new report from the National Research Council, which recommends improvements for EPA's final assessment. The report finds that EPA supports its conclusions that formaldehyde can cause irritation to the eyes, nose, and throat; lesions in the respiratory tract; and genetic mutations at high concentrations. Furthermore, the report finds that the evidence is sufficient for EPA to conclude that formaldehyde exposures are a cause of cancers of the nose, nasal cavity, and upper throat. However, the draft assessment has not adequately supported its conclusions that formaldehyde causes other cancers of the respiratory tract, leukemia, or several other noncancer health outcomes. Also, the assessment should consider additional studies to derive noncancer reference concentrations (RfCs), which are estimates of lifetime concentrations to which someone could be exposed without appreciable risk of particular adverse health effects.

Formaldehyde is an important industrial chemical used to produce a wide array of materials, but it is also generated naturally by the human body. When inhaled, it is absorbed primarily at the site of first contact, where it is metabolized and reacts with cellular components; thus, inhaled formaldehyde remains predominantly in the tissue that lines the airways.

Given the pervasive exposure of the general population to some concentration of formaldehyde, federal agencies tasked with protecting public health are concerned about the health effects. In June 2010, EPA released its draft health assessment of formaldehyde, and a Research Council committee that wrote the report reviewed the assessment and key literature to determine whether EPA's conclusions were supported. The committee did not perform its own assessment or conduct additional literature searches.

Overall, the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies. Moreover, many of the general problems with the EPA formaldehyde health assessment have been identified by other Research Council committees that reviewed other EPA chemical assessments in recent years. For instance, there have been recurring problems with clarity and transparency of the methods, even though the documents have grown considerably in length. The committee concluded that if the methodologic issues are not addressed, future assessments may suffer from the same general problems highlighted in this report.

Various cancerous and noncancerous health effects attributed to formaldehyde were evaluated in EPA's draft assessment, including:

Leukemia and lymphoma. The committee did not support EPA's grouping of all types of leukemias and lymphomas because it combined diverse cancers that are not closely related. Although EPA presented an exhaustive description of studies and speculated extensively on how formaldehyde reacts in the body, the determinations of causality are not supported in the assessment. EPA should revisit its arguments and include detailed descriptions of the criteria that were used to weigh evidence and assess causality.

Respiratory tract cancers. The committee found that EPA's assessment had sufficient evidence to conclude that formaldehyde causes cancer in the nose, nasal cavity, and nasopharynx (upper throat). However, the evidence regarding the chemical's relationship to cancer in other sites in the respiratory tract was considered insufficient.

Asthma. EPA should strengthen its discussion of asthma to reflect current understanding of the disease, as the term "asthma" is commonly applied to a broad category of respiratory diseases, the committee said. EPA's assessment provides little discussion about how asthma could be caused or exacerbated by formaldehyde exposure.

Nervous system function. EPA's conclusion that formaldehyde harms the nervous system was overstated, the committee said. The human data used as evidence are insufficient and the candidate animal studies deviate substantially from testing guidelines and common practice.

Reproduction and development. The report finds that the evidence is insufficient to support EPA's conclusion that there is a "convincing" relationship between formaldehyde exposure and adverse reproductive outcomes, such as infertility in women. Rather, the human data suggest a pattern of association -- meaning the evidence indicates there could be an increased risk for an adverse reproductive outcome but uncertainty limits any conclusion. Although the animal data also suggest an effect, EPA should weigh the positive and negative results more rigorously, evaluate study quality more critically, and consider carefully potential confounding factors.

In addition, the report suggests improvements to the development and presentation of EPA's calculated RfC values and strongly encourages a more informative approach similar to that previously proposed by other Research Council committees and used in other recent EPA assessments. The committee recommended that EPA use an appropriate graphical display to help identify a central value, isolate especially high or low values that might not be consistent with the literature, and improve the ability of the assessment to make a compelling case that the RfC proposed is appropriate.

The report also offers general recommendations to help revise the formaldehyde draft assessment, including rigorously editing to reduce the volume of text, adding clear and concise statements on the methods used, standardizing evidence tables, and thoroughly evaluating all critical studies for strengths and weaknesses. The committee also provided a "road map" for improving the assessment process in general.

The study was sponsored by the U.S. Environmental Protection Agency. The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council make up the National Academies.

They are independent, nonprofit institutions that provide science, technology, and health policy advice under an 1863 congressional charter.

Committee members, who serve pro bono as volunteers, are chosen by the Academies for each study based on their expertise and experience and must satisfy the Academies' conflict-of-interest standards. The resulting consensus reports undergo external peer review before completion. For more information, visit <http://national-academies.org/studycommitteeprocess.pdf>.

A committee roster follows.

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Formaldehyde are available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at <http://www.nap.edu>. Reporters may obtain a copy from the Office of News and Public Information (contacts listed above).

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NATIONAL RESEARCH COUNCIL
Division on Earth and Life Studies
Board on Environmental Studies and Toxicology

Committee to Review the Draft IRIS Assessment on Formaldehyde
Review of EPA's Draft Assessment of Formaldehyde - page 3

(MORE)
(MORE)

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(See attached file: Formaldehyde Prepub.pdf)